

REMARKS

Claims 1-46 are pending. Claims 7-10 and 40 were objected to. Reconsideration of the claims based on the below comments is respectfully requested.

35 U.S.C. § 103(a) Rejections

Independent Claims 1 and 39

The pending claims have three independent claims (claims 1, 22 and 39). Claim 1 recites, *inter alia*, (a) “a single calibration input element adapted to permit a user to input the calibration number, one digit at a time, associated with the test sensor”; (b) “a processor electronically coupled to the single calibration input element...”; and (c) “a user display electronically coupled to the processor for displaying digits to be selected by a user inputting the calibration number....”

Claim 39 recites, *inter alia*, (a) “a single calibration input element adapted to permit the user to select digits for inputting a multiple-digit calibration number, one digit at a time”; and (b) “a processor electronically coupled to the single calibration input element and the user display, the processor prompting the user to input each of the digits of the calibration number, one at a time, the processor receiving the inputted calibration number and adjusting the at least one adjustable parameter of the concentration equation according to the stored adjustment corresponding to the inputted calibration number.”

As acknowledged in the Office Action, U.S. Patent 5,856,195 to Charlton (“Charlton”) “does not teach a single calibration input element for permitting a user to input the calibration number, one digit at a time, associated with the test sensor”, a specific limitation in independent claims 1 and 39. *See* Page 2 of the Office Action. The other applied reference of U.S. Patent No. 6,560,471 to Heller et al. (“Heller”) also does not disclose, teach or suggest a single calibration input element adapted to permit a user to input the calibration number, one digit at a time, of claims 1 and 39.

Rather, Heller discloses an “input device (e.g., a keypad, an optical signal receiver, or a port for connection to a keypad or computer) [that] is [directly] incorporated in the on-skin sensor control unit 44, or indirectly by inputting the calibration data into the receiver/display unit 46, 48; and transmitting the calibration data to the on-skin sensor control unit 44.” Col. 50 at lines 17-24. This is exactly the type of device that the present invention is addressing and improving upon. Specifically, the present application states that “[i]n many prior art devices, the

6 has a plurality of buttons 8b-e (FIG. 1) for inputting the calibration number into the test device.” Page 3, line 30-31 of the present application.

Furthermore, the combination of the Charlton device with the receiver/display unit of Heller is improper. In Charlton, the calibration-encoded label “is used to automate the process of information transfer about the lot specific reagent calibration assignment for associated sensors.” Col. 5, lines 29-35 of Charlton (emphasis added). “The calibration encoded label 70 is read at any angular position and deciphered by the sensor meter 10 without any user intervention.” Col. 5, lines 39-42 of Charlton (emphasis added). Charlton specifically refers to the calibration input element that automates the method of calibration as a feature of the invention. Col. 5, lines 29-35 of Charlton. Heller, on the other hand, discloses the opposite method of calibration by requiring the user to manually input the data via a keypad, an optical signal receiver, or a port for connection to a keypad or computer. See col. 50, lines 17-24 of Heller. It is unclear on how the automated auto-calibration Charlton device could be combined with the manual auto-calibration device of Heller.

Furthermore, there is no motivation to combine the Charlton device with the receiver/display unit of Heller in an attempt to read on the pending claims. “When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.” *Rouffet*, 149 F.3d at 1355, 47 U.S.P.Q.2d at 1456, (citing *In re Geiger*, 815 F.2d 686, 688, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987)). Evidence of a suggestion, teaching, or motivation to combine “must be clear and particular.” See *Ex parte Maruyama*, 2001 WL 1918556, *3 (Bd. Pat. App. & Inter. 2001), (citing *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998)).

Therefore, independent claims 1 and 39 are not rendered obvious by Charlton, Heller or the combination thereof and, thus, should be in a condition for allowance.

Independent Claim 22

Claim 22 recites, *inter alia*, (a) “prompting a user, via a user display, to enter a digit of the calibration number”; (b) “receiving input from the user, via a single calibration input element, indicative of the calibration number, one digit at a time”; and (c) “determining the analyte concentration in the sample in response to receiving the calibration number from the user and measuring the reaction.”

As acknowledged in the Office Action, Charlton "does not teach prompting a user, via a user display, to enter a digit of the calibration number" and "receiving input from the user, via a single calibration input element, indicative of the calibration number, one digit at a time", a specific limitation in independent claim 22. *See* page 8 of the Office Action. For the same reasons as discussed for independent claims 1 and 39, claim 22 is not rendered obvious by Charlton, Heller or the combination thereof and, thus, should be in a condition for allowance.

Dependent Claims


Claims 7-10 and 40 were objected to. Dependent claims 2-21, 23-38 and 40-46, which depend either directly or indirectly on independent claim 1, 22 or 39, should also not be rendered obvious over Charlton, Heller, or the combination thereof, for at least the same reasons as discussed above in connection with independent claims 1, 22 and 39. Thus, claims 2-21, 23-38 and 40-46 also should be in a condition for allowance.

Conclusion

The Applicant submits that the claims are in a condition for allowance and action toward that end is earnestly solicited. It is believed that no fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Bayer Healthcare LLC Deposit Account No. 13-3375(MSE-#2672).

Respectfully submitted,

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John C. Gatz, Reg. No. 41,774
JENKENS & GILCHRIST
225 West Washington Street
Suite 2600
Chicago, Illinois 60606
(312) 425-3900 – telephone
(312) 425-3909 - facsimile

ATTORNEY FOR APPLICANT